REMARKS

This Amendment is in reply to the Final Office Action mailed December 14, 2004, for which an unextended response is due March 14, 2005. A Request for Continued Examination (RCE) is filed herewith. Claims 1-30 are currently pending in the instant application. Claims 1-3, 15, 17 and 26-30 have been cancelled, without prejudice. Applicants respectfully reserve the right to pursue the subject matter of said canceled claims in a future continuing application. The allowance of claims 8-13 is noted with appreciation. Claims 4, 6, 14, 16 and 20 are currently amended in order to advance prosecution on the merits. It was noted in the outstanding Final Office Action that claims 4-7, 14, 16, 21-25, 29 and 30, while objected to as being dependent upon a rejected base claim, would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No new matter has been added.

Claim 4 has been rewritten in independent form and includes all of the limitations of the rejected base claim in its original format (*i.e.*, Claim 1 prior to the amendment filed September 27, 2004 that restricted Claim 1 to particular transcription promoters) and any intervening claims (*i.e.*, Claim 3). Amended Claim 4 states that the claimed plasmid expression vector comprises at least one gene encoding a carboxy-terminal truncated gB protein comprising the amino terminal 707 amino acids of the wild type gB protein, and said gene or genes is operably linked to a transcription promoter. No new matter has been added.

Claim 6 has been rewritten in independent form and includes all of the limitations of the rejected base claim in its original format (*i.e.*, Claim 1 prior to the amendment filed September 27, 2004 that restricted Claim 1 to particular transcription promoters) and any intervening claims (*i.e.*, Claim 2). Amended Claim 6 states that the claimed plasmid expression vector comprises at least one gene encoding the HSV protein, gD, and said gene or genes is operably linked to a transcription promoter. No new matter has been added.

Claim 14 has been rewritten in independent form and includes all of the limitations of the rejected base claim in its original format (*i.e.*, Claim 1 prior to the amendment filed September 27, 2004 that restricted Claim 1 to particular transcription promoters). Amended Claim 14 states that the claimed method for inducing immune responses in a vertebrate against HSV epitopes comprises introducing a plasmid expression vector into a tissue of a vertebrate, wherein said vector comprises at least one gene encoding at least one HSV protein or truncated protein operably linked to a transcription promoter. No new matter has been added.

Claim 16 has been amended to depend upon currently amended Claim 14, stating that the claimed method for inducing immune responses comprises introducing a plasmid expression vector comprising a gene which encodes an HSV protein selected from a group consisting of gB, gC, gD,

gH, gL, ICP27, and gB. The dependency of this amended claim provides for all the limitations of the rejected base claim in its original format (*i.e.*, Claim 1 prior to the amendment filed September 27, 2004 that restricted Claim 1 to particular transcription promoters) and any intervening claims (*i.e.*, Claim 2). No new matter has been added.

Claim 20 has been amended to change dependency of said claim to Clam 19 from Claim 18, correcting an editorial oversight. No new matter has been added.

Applicants request that the above amendments to the claims be entered. Any omission of subject matter by amendment of the claims is done without prejudice to pursuing the same in a continuation or divisional application.

Rejection of Claims 1-3, 15, 17 and 26-28 under 35 U.S.C. § 103(a)

Claims 1-3, 15, 17 and 26-28 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Burke (Reviews of Infectious Diseases 13 (Suppl. 11):S906-911(1991)) in view of the state of the prior art disclosed in the instant application (*e.g.*, page 14, lines 16-18 and 30-34, and page 24, line 16 through page 25, line 7). The Examiner takes the position that "it would have been obvious for one of ordinary skill in the art at the time the invention was made to use any of the admittedly old promoters in the expression vector of Burke to achieve higher levels of gene expression." Applicants respectfully traverse.

However, in order to advance the prosecution on the merits, Applicants have canceled claims 1-3 and 26-28 without prejudice to pursing the subject matter of any canceled claim in a separate continuing application. Accordingly, Applicants respectfully request the reconsideration of the instant rejection regarding claims 1-3 and 26-28.

Applicants have also canceled rejected claims 15 and 17 in favor of the continued prosecution of previously presented claims 18-20, currently rejected under 35 U.S.C. § 102(b) as being anticipated by Burke, *supra* (see below). Claim 18 is drawn to a vaccine for inducing an immune response against HSV which comprises a plasmid expression vector and a pharmaceutically acceptable carrier, wherein said plasmid expression vector comprises at least one gene encoding at least one HSV protein or truncated protein, said gene or genes being operably linked to a transcription promoter. Claims 19 and 20 ultimately depend upon claim 18, specifically drawn a vaccine of claim 18 wherein the plasmid expression vector comprises a gene which encodes either an HSV protein selected from the recited Markush group (claim 19) or, more specifically, a carboxy-terminal truncated HSV gB protein (claim 20). Claims 18-20 are similar to rejected claims 15 and 17, except claims 15 and 17 ultimately depended upon claims 1 and 2, restricting the plasmid expression vector to comprising at least one gene encoding an HSV protein (or truncated form)

operably linked to one of the recited transcription promoter. Due to the similarity in subject matter between pending claims 18-20 and rejected claims 15 and 17, Applicants will respond to the instant obviousness rejection in the event a similar rejection is issued to the currently pending vaccine claims (claims 18-20).

Burke discloses the advantages of using recombinant DNA technology to produce viral glycoproteins for the generation of a HSV subunit vaccine. The plasmid diagrammed in Figure 1 is used to stably transfect a cell line for production of the HSV glycoprotein encoded by the gene comprised within the plasmid. Said protein is secreted into the growth medium, purified and used to immunize guinea pigs against HSV. Burke's contribution over the prior art was to show that more defined viral glycoproteins could be produced for immunization regimens against HSV, rather than immunizing with a mixture of HSV glycoproteins purified from cells infected with HSV. Absent from Burke is any discussion or suggestion of the use of the plasmid vector diagrammed in Figure 1 as a polynucleotide vaccine, alone or in combination with a pharmaceutical carrier, for the purpose of inducing anti-HSV antibodies or a protective immune response against HSV. In the alternative, the article actually teaches away from this concept by further highlighting the role that vaccine delivery vehicles play in the immunogenicity of protein-based vaccines, concluding that choice of delivery vehicle is a critical factor when designing subunit vaccines. Thus, Applicants assert that there is no teaching, suggestion, incentive or reference in the cited reference, or in the form of generally available knowledge, that one having ordinary skill in the art would have been motivated to make the claimed invention and would have had a reasonable expectation of success in doing so.

Rejection of Claims 18-20 under 35 U.S.C. § 102(b)

Claims 18-20 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Burke, *supra*. It is stated that "[t]he plasmid disclosed in Figure 1 (page S907) has all of the structural features of the recited claims." Applicants respectfully traverse.

In order to anticipate a claim, the cited reference must teach each and every element of the claim. As described previously, Claim 18 is drawn to a vaccine for inducing an immune response against HSV which comprises a plasmid expression vector and a pharmaceutically acceptable carrier, wherein said plasmid expression vector comprises at least one gene encoding at least one HSV protein or truncated protein, said gene or genes being operably linked to a transcription promoter. Claims 19 and 20 ultimately depend upon claim 18, specifically drawn a vaccine of claim 18 wherein the plasmid expression vector comprises a gene which encodes an HSV protein selected from the recited Markush group (claim 19) or a carboxy-terminal truncated HSV gB protein (claim

20). Applicants assert that Burke (*supra*) does not teach each and every element of these vaccine claims, in particular the combination of a plasmid expression vector comprising a gene encoding an HSV protein and a pharmaceutical carrier for administration to a host for induction of an immune response against HSV. Furthermore, Applicants assert that not only are the rejected claims novel over the cited reference, but for reasons presented in detail above, they are also non-obvious.

In light of the arguments presented herein, Applicants respectfully request withdrawal of the rejection of claims 18-20 under 35 U.S.C. § 102(b).

In view of the amendments and comments herein, Applicants respectfully take the position that all claims are in proper form for allowance and earnestly solicit a favorable action on the merits. The Examiner is invited to contact the undersigned attorney if clarification is required on any aspect of this response, or if any of the claims are considered to require further amendment to be placed in condition for allowance after entry of this Amendment.

Respectfully submitted,

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